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(54) Medical container with electrolyte solution stored therein

(57) A medical container with an electrolyte solution stored therein is disclosed. It is formed of a resin-made container main body, a base solution compartment, at least one isolated compartment or connected compartment, and an openable portion. The base solution compartment is arranged in the container main body and is filled with the electrolyte solution in a state steam-sterilized together with the container main body. The isolated compartment or connected compartment is arranged in the container main body, is isolated from the base solution compartment by an isolation wall interposed therebetween, and is filled with a bicarbonate. The openable portion permits aseptic communication between the base solution compartment and the isolated compartment or connected compartment by an operation from an outside of the container main body at the time of use. The openable portion is formed at at least a part of the isolation wall. This medical container makes it possible to store an electrolyte solution, dialysate or the like at a pH value close to that of the body fluid without inducing kidney problems, diarrhea, vomiting or the like due to acidosis or the like upon use.

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state. Namely, the bicarbonate is filled in a solid alkali metal salt form in the connected container 115. The alkali metal in such an alkali metal salt substitutes for a portion of the corresponding alkali metal salt to be added to the base solution 114 which is in turn to be filled in the container main body 112. In this embodiment, it is desired to fill sodium bicarbonate or sodium carbonate in the connected container 115 in an amount sufficient to prepare a peritoneal dialysate of pH 7 or higher, especially of from pH 7.9 to pH 9.0 (this pH means a value when a 1:30 aqueous solution is prepared). The sodium salt to be added to the base solution 114 should be reduced by an amount equivalent to the sodium salt to be filled in the connected container 115.

As the base solution 114 is filled in the container main body 112 and the bicarbonate salt 116 is separately filled in the connected container 115, the base solution 114 is filled as a solution of a composition calculated by subtracting a lactate and a sodium salt in amounts as much as the theoretical amount of sodium in the bicarbonate 116.

Before being mixed with the bicarbonate 116, the pH of the base solution 114 is desirably 5.5 or lower, particularly 5.3 or lower, with 5.0 or lower being more desired. Such acidification of the base solution 114 can be easily achieved owing to the separation of the bicarbonate 116. When the base solution 114 is maintained at a pH in the above range, the potential problem that glucose or the like in the base solution 114 could undergo a quality modification is extremely reduced even when the base solution 114 is heated during autoclave sterilization.

The container main body 112 is provided with delivery ports 123. The base solution 114 is filled through one of the delivery ports 123. Both the delivery ports 123 are then closed in a liquid-tight fashion, followed by autoclave sterilization with the connected container 115 connected to the container main body 112. This autoclave sterilization is conducted based on the standards for steam sterilization as specified in the Pharmacopoeia of Japan. An ordinary autoclave is used for the autoclave sterilization. The autoclave sterilization is performed at a temperature of from 100 to 130°C after purging the interior of the autoclave, for example, with an inert gas.

In the peritoneal dialysate container 111 constructed as described above, the bicarbonate 116 does not undergo decomposition during sterilization even under the severe heating conditions for the sterilization so that the bicarbonate 116 is stored in its filled state in the connected container 115. During storage of the container 111, the base solution 114 and the bicarbonate 116 are stored within the container main body 112 without decomposition. These peritoneal dialysate containers 111 can therefore be supplied, as are, not only to hospitals but also to patients' homes.

Peritoneal dialysate containers 111 of this embodiment were evaluated as will be described hereinafter. In each peritoneal dialysate container 111, 5.000 g of sodium bicarbonate powder were filled in the connected container 115. The base solution 114 was prepared with the above-described electrolytes and saccharide contained in the corresponding ranges also described above. Two liters of the base solution 114 were filled in the container main body 112. The seal portions 113 and 122 were formed in the above-described manner, followed by autoclave sterilization at 121°C.

The pealable seal portion 122 of each peritoneal dialysate container 111 was opened and the sodium bicarbonate was quantitated based on the Pharmacopoeia of Japan. As a result, changes in the amounts of sodium bicarbonate in all the peritoneal dialysate containers 111 before and after the autoclave sterilization were within ±5% by weight.

Upon use of the peritoneal dialysate container 111, the pealable seal portion 122 is pealed from the outside of the container main body 112 to communicate the interior of the container main body 112 and that of the connected container 115 with each other. The base solution 114 and the bicarbonate 116 are hence mixed, whereby the dialysate is prepared in the container main body 112.

As is illustrated in FIG. 13, to apply the peritoneal dialysate to a patient 130 subsequent to the peeling of the pealable seal portion 122, a connecting tube 132 is brought into communication with the interior of the container main body 112 via a communication needle 131 pierced through one of the delivery ports 123 of the container 112. The connecting tube 132 is connected to a catheter 133, which is in turn connected to the interior of the abdominal cavity 134 of the patient 130. As a result, the dialysate in the container main body 112 is allowed to flow into the abdominal cavity 134 so that dialysis is performed.

The Japanese application from which this application claimed priority under Article 87 EPC is filed herewith and the contents are incorporated in their entirety into this document.

The container of this invention may be used for any type of solution where one component of the solution must not be mixed with other components prior to use and so this invention is not limited purely to the types of medical solutions mentioned herein.

Claims

1. A container comprising:

   a container main body with a base solution compartment arranged therein and filled with an electrolyte solution and an isolated compartment filled with an isolated component arranged in said container main body and isolated from said base solution compartment by an isolation wall interposed therebetween;

openable means for permitting aseptic communication between the base solution compartment and the isolated compartment, said openable means being formed in at least a part of the isolation wall.

2. A container according to claim 1, wherein said openable means is formed either of a separable seal portion or weak seal portion separable from said outside of said container main body.

3. A container according to claim 1 or claim 2, wherein said container main body is equipped with an inner layer made of a blend of polyethylene and polypropylene.

4. A container according to any preceding claim, wherein said isolated compartment has been subjected to radiation sterilization by for example γ rays, electron beams or ultraviolet rays.

5. A container according to any one of claims 1 to 4, wherein either:

(i) radiation sterilization of said isolated compartment is designed to be electron beam sterilization at an accelerating voltage of 1 MeV or lower, and said isolated compartment is equipped with a wall having a thickness of from 10 to 1,600 μm; or
(ii) radiation sterilization of said isolated compartment is designed to be ultraviolet ray sterilization, and said isolated compartment or connected compartment is equipped with a wall having a thickness of from 10 to 100 μm, an ultraviolet transmission of at 60% or higher at a wavelength of 250 nm when the thickness is 10 μm, and a density of from 0.95 to 0.85 g/cm^3.

6. A container according to any preceding claim, wherein, when said base solution compartment and said isolated compartment are communicated with each other, said electrolyte solution and said isolated component are mixed together into:

a) an infusion solution having a pH in a range of from 5.5 to 7.5 and for example containing an HCO_3^- at a concentration of from 1 to 65 mEq/ℓ; or
b) peritoneal dialysate containing:

an HCO_3^- at a concentration of from 1 to 40 mEq/ℓ,
an Na^+ at a concentration of from 90 to 150 mEq/ℓ,
a Ca^{2+} at a concentration of from 0 to 6 mEq/ℓ,
an Mg^{2+} at a concentration of from 0 to 3 mEq/ℓ,
a Cl^- at a concentration of from 90 to 135 mEq/ℓ,
a CH_3COO^- or $CH_3CH(OH)COO^-$ at a concentration of from 0 to 40 mEq/ℓ, and
one or more of saccharides; and

having:

an osmotic pressure in a range of from 300 to 680 mOsm/ℓ, and
a pH in a range of from 5.7 to 7.5; or

c) an organ-preserving solution containing:

an HCO_3^- at a concentration of from 1 to 50 mEq/ℓ; and

having:

an osmotic pressure in a range of from 250 to 400 mOsm/ℓ, and
a pH in a range of from 3 to 10.

7. The container according to any one of the preceding claims, wherein the container is made from at least one resin material, which at least one resin in selected for its permeability to particular compounds or physical stimuli.

8. The container according to any one of the preceding claims, wherein the isolated component is a solid, and preferably is a solid which will form HCO_3^- ions when mixed with the electrolyte.

9. The container according to any one of the preceding claims, wherein the isolated component and electrolyte solution require sterilization by different means when in the container.

10. Use of a container having a container main body which includes a base solution compartment and an isolated compartment separated by an isolation wall therebetween, operable means being provided to selectively allow fluid connection between said compartments, to store a medical solution where one component of the medical solution is maintained in the isolated compartment until mixed with another component of the medical solution in the base solution compartment immediately prior to use of the medical solution; and optionally being the container of any one of the preceding claims.